



United States
Department of
Agriculture

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-05

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
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Subject: Issuance of a Conditional License for Treponema Bacterin

To: Area Veterinarians in Charge, VS
State Veterinarians
Veterinary Services Management Team
Directors, Center for Veterinary Biologics

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Novartis Animal Vaccines, Inc., ImmTech Division, Establishment No. 480, Bucyrus, Kansas, for the manufacture and distribution of Treponema Bacterin.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or special circumstance. The special circumstance addressed here is the need for a product to aid in the reduction of papillomatous digital dermatitis, caused by *Treponema* spp. Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy.

The conditional license was issued on the basis that Novartis Animal Vaccines, Inc., ImmTech Division, has demonstrated that the product has a reasonable expectation of efficacy. Safety of the product has been established through field safety trials. Novartis Animal Vaccines, Inc., ImmTech Division, has provided a written commitment to APHIS to complete studies to demonstrate the efficacy of this product and to conduct any other work required for full licensure. APHIS will evaluate their progress later this year. The conditional license will expire one year from the date of the license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.



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